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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,943	05/03/2006	Daniel C. Carter	P07931US06/BAS	5248

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,943	Applicant(s) CARTER ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-34 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 and 13-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/03/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-10,12-34 are pending.

Response to restriction requirement filed 11/12/2008 is acknowledged. Applicant elected Group I.10 claims 1-5 and 10,12 directed to albumin subdomain IIIA. Insofar as applicants have not specifically pointed out the reasons supporting the statement of the traversal, applicants' election is taken to be without traverse. See MPEP 818.03(a). The restriction requirement is still deemed proper and is therefore made FINAL. Claims 6-9,11,13-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 03/03/2008 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Abstract

3. The abstract of the invention is not descriptive. The title and abstract do not reflect the elected invention. A new abstract is required which are clearly indicative of the invention to which the elected claims are directed. An abstract on a separate sheet is required.

Claim Objections

4. Claims 2,3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 1 is directed to determining structural coordinates with the root mean square deviation of not more than 1.15 angstroms, whereas claims 2 and 3 are directed to a larger range of root mean square deviation. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Specification Objections

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Specification does not disclose region IIIA as claimed. See p. 11, lines 6-11. For example, residues at positions 422,445,450,452,490,492 addressed in the claims (claim 10) are not in the disclosure.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5,10,12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claim 1, step a), is directed to determining structural coordinates with the root mean square deviation of not more than 1.15 angstroms from coordinates in Tables II or III ; however, Tables II and III do not provide any structural coordinates; thus it is not clear how to determine the deviation as claimed.

B. Claim 1, step b), is directed to a method step selected from a group consisting of steps i)-vi). However, for potential steps iv),v), vi) there no method steps are recited; thus it is not clear what method steps are to be performed.

C. Claims 4,5 lack antecedent basis as they refer to “the angles (psi and phi angles respectively); however such angles are not addressed in the base claim 1.

D. Claim 10 is indefinite as it addresses a plurality of residues which are repeated twice with different amino acids at the same residue position. See residues # 387,391,450, for example.

Further, some residues in claim 10 conflict with the disclosure: thus, for position 383 the claim cites E383 compared to R383 in the specification, for position 391 the claim cites A391 compared to N391 in the specification, etc.

E. Claim 12 addresses use of coordinates (of what?) at positions shown in Tables I and II. However, Table 1 is devoid of any positions. Table II provides positions of domains having interactions with particular drug ligands. However, there are numerous instances of addressing domain IB, in each instance, the set of residues varies and thus, it is not possible to identify use of which coordinates is being addressed.

Claim Rejections - 35 U.S.C. § 101

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 1-5,10,12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a computational method of evaluation of ability of compounds to “associate” with a protein subdomain. No physical transformation is addressed in the claims. Nor there is any recitation of a tie to another category of invention (the step of “constructing a computer model” is not viewed as necessarily involving use of a computer).

To qualify as a statutory process, the claims should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state or thing. In the instant case, claims do not recite any physical

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transformation step. Further, there is no step in the claims that recites a tie to another category of invention. Therefore, the claims are drawn to non-statutory subject matter for failing to recite a step that ties the method to another category of invention.

Further, there is no practical application to produce a real-world result as a result of the method as claimed. A tangible result requires that the claim must set forth a practical application to produce a real-world result. In the instant case, there is no tangible output of a result of the claimed method.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5,10,12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to determining structural coordinates with the root mean square deviation of not more than 1.15 angstroms from in Tables II or III; however, Tables II and III do not provide any structural coordinates; thus, at the time the application was filed, had possession of the claimed invention

Claim Rejections - 35 USC § 102 103.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5,10,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (US patent 5780594; reference provided by applicant) in view of Colmenarejo (Medicinal Research Reviews, Vol. 23, No. 3, 275-301, 2003; reference provided by applicant) and Floriano (US 2002/0099506).

Carter (the inventor of the instant invention as well) provides structural information on albumin subdomains obtained from crystallographic means (col. 3, last

full paragraph). Carter teaches that albumin subdomain IIIA is one of albumin subdomains primarily responsible for binding properties of serum albumin (col. 2, last paragraph) and that the binding cavity in domain IIIA “the most active and accommodating on the human serum albumin, and many ligands have been found to preferentially bind in this region” (col. 4, first paragraph).

Carter does not teach use of computer modeling to identify “ability of compounds to associate) with albumin or its complexes as instantly claimed.

Floriano et al teach method of computer modeling to predict ligand-protein interactions wherein a binding region of the protein is identified using the structural information for the protein, and computer modeling is used to identify plurality of preferred binding conformations for potential ligands the preferred binding conformations are optimized using annealing molecular dynamics technique and the ligands with the lowest calculated binding energy in the optimized preferred binding conformations are selected. See claims 1-8.

Colmenarejo teach *in silico* methods for prediction of drug-binding strengths to human serum albumin (see Abstract).

In *KSR Int 'l v. Teleflex*, the Supreme Court, in rejecting the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, indicated that

The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

Applying the KSR standard of obviousness to Carter and Floriano, Examiner concludes that the nature of the problem to be solved – evaluating potential of compounds to associate with albumin may lead inventors to look at references relating to possible solutions to that problem. Therefore, given the importance of the particular subdomain IIIA of albumin as being known as primarily responsible for binding properties of serum albumin, and given the developing use of computational techniques to drug-binding strengths to human serum albumin, it would have been obvious to use computational methods of Floriano for modeling ligand-protein interactions to identify ligands that interact with this particular albumin subdomain.

With respect to claims 10,12, Carter teach that binding region IIIA spans between residues 375 and 495 (col. 4, last paragraph). Thus, a three dimensional model would include all of the residues as instantly addressed, and it would be obvious to an artisan to select particular residues of interest.

Double Patenting

10. Claims 1-7 of this application conflict with claim1-7 of Application No. 10/555761. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during

pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Conclusion.

11. No claims are allowed

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631

mlb